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EXHIBIT D

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. ELI LILLY & COMPANY, INC., ET AL., Defendants	: : : : : : : : : :	CIVIL ACTION NO. 07-1083
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MEMORANDUM AND ORDER

PRATTER, J.

JUNE 26, 2007

The Commonwealth of Pennsylvania filed this lawsuit in the Philadelphia County Court of Common Pleas in February 2007 alleging, inter alia, that the defendant pharmaceutical companies caused the submission of fraudulent claims for prescription medications, as well as injuries resulting from the medications' side effects. The Defendants timely filed a Notice of Removal, quickly followed by a "Joint Motion to Stay All Proceedings Pending Transfer by the Judicial Panel on Multidistrict Litigation." The Commonwealth opposed the stay motion on the grounds that the Court lacks subject matter jurisdiction over the case, and the Commonwealth submitted its Motion to Remand for the Court's consideration. The Court denied the Motion to Stay insofar as the Court determined to hear the Motion to Remand.¹ The case is otherwise stayed. The Defendants oppose remand. For the reasons discussed more fully below, the Court will grant the Motion to Remand.

The Complaint states the following Pennsylvania statutory and common law claims:

¹ All parties have been ably represented by counsel in this matter and the Court again compliments each on their fine, thought-provoking written and oral presentations.

Medicaid fraud under 62 P.S. § 1407; Pennsylvania Assistance Contract for the Elderly (“PACE”) fraud under 72 P.S. § 3761-521; Recovery by the Commonwealth as *parens patriae* of treatment costs for Medicaid and PACE participants injured by the Defendants’ drugs due to a failure to warn; negligence; breach of warranty; fraud and misrepresentation; misrepresentation under Restatement (Second) of Torts § 402B; and unjust enrichment. The Commonwealth does not allege any cause of action created by federal law.

SUBJECT MATTER JURISDICTION

Federal courts are courts of limited jurisdiction. See Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994). A federal court may exercise subject matter jurisdiction over “all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. Any civil action over which the district courts have original jurisdiction rooted in a claim or right arising under the Constitution, treaties or laws of the United States are removable without regard to the citizenship or residence of the parties. 28 U.S.C.A. § 1441. As many courts and commentators have recognized, “[t]he most difficult single problem in determining whether federal question jurisdiction exists is deciding when the relationship of the federal law to a case is such that the action may be said to be one ‘arising under’ that law.” 13B Wright, et al., Federal Practice and Procedure 17-18 (2d ed. 1984).

A case “aris[es] under” federal law within the meaning of § 1331 if “a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal law.” Empire Healthchoice Assurance, Inc. v. McVeigh, 126 S. Ct. 2121, 2131 (2006) (citing Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust for Southern Cal., 463 U.S. 1, 27-28

(1983)).

The Supreme Court has long recognized that in certain cases federal question jurisdiction will lie over state-law claims that implicate significant federal issues or “turn on substantial questions of federal law.” Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Manufacturing, 545 U.S. 308, 312 (2005) (citing Hopkins v. Walker, 244 U.S. 486, 490-91 (1917)). This “slim category” of cases, Empire, 126 S. Ct. at 2137, reflects the “commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues,” Grable, 545 U.S. at 312.

However, “the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction.” Merrel Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 813 (1986). To determine whether a state law claim “arises under” federal law for purposes of subject matter jurisdiction, the Court must inquire whether “a state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” Grable, 545 U.S. at 314. Thus, even if the Complaint raises a disputed and substantial federal issue, the exercise of jurisdiction must be “consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331.” Id. at 313. Defendants, as the removing parties, bear the burden of proving that removal is proper. Dukes v. United States Healthcare, Inc., 57 F.3d 350, 359 (3d Cir. 1995).

In their briefing and during oral argument, the parties appeared to tacitly acknowledge

that Grable and Empire present the Court with the most instructive judicial guidance on the issue at hand, though, of course, the Defendants urge the Court to adopt the analysis and application of Grable by the undeniably able Eastern District of New York, while the Commonwealth urges following the lead of the courts for the District of Alaska and the Western District of Texas. See footnote 3, infra.

In Grable, the Supreme Court held that removal was proper because the plaintiff's claim depended upon the interpretation of a disputed federal statutory provision. Grable involved real property belonging to Grable & Sons Metal Products, Inc., which the Internal Revenue Service seized to satisfy a federal tax deficiency. 545 U.S. at 310. Grable received notice of the seizure by certified mail, but later sued in state court to quiet title on the grounds that the IRS had conveyed the seizure notice improperly, rendering the subsequent sale invalid. Id. at 311. The governing statute, 26 U.S.C. § 6335(a), provides that "notice in writing shall be given . . . to the owner of the property . . . or shall be left at his usual place of abode or business." Grable maintained that § 6335(a) required personal service, not service by certified mail. 545 U.S. at 311.

Upholding the federal court's jurisdiction, the Court observed that whether Grable received notice adequate under § 6335(a) was "an essential element of [Grable's] quiet title claim"; indeed, it appeared to be the only contested issue in the case. Id. at 315. The Court further noted that the meaning of the federal tax provision "is an important issue of federal law that sensibly belongs in federal court." Id. Grable thus "presented a nearly 'pure issue of law,' one 'that could be settled once and for all and thereafter would govern numerous tax sale cases.'" Empire, 126 S. Ct. at 2137.

By contrast, in Empire, a health insurance carrier for federal employees, Empire Healthchoice Assurance, Inc., brought an action in federal court against a former enrollee's estate, seeking reimbursement of insurance benefits on the ground that the enrollee had recovered damages for his injuries in a state-court tort action. 126 S. Ct. at 2127. Empire maintained that its contract-derived claim implicated "uniquely federal interest[s]," because (1) reimbursement directly affected the United States Treasury and the cost of providing health benefits to federal employees; and (2) Congress had expressed its interest in maintaining uniformity among the states on matters relating to federal health-plan benefits. Id. at 2130.

While acknowledging that distinctly federal interests were involved, Empire upheld the dismissal of the case for lack of subject matter jurisdiction on the grounds that "countervailing considerations control." Id. at 2134. In particular, the reimbursement right in question, predicated on a contract authorized by federal statute, was "not a prescription of federal law," and Congress considered jurisdictional issues in enacting the federal statute in question and conferred jurisdiction "where it found it necessary to do so." Id. The Court emphasized that such evidence of congressional intent was "of prime importance." Id. Distinguishing Grable, the Court further noted that Empire's reimbursement claim was "fact-bound and situation specific," whereas Grable presented a nearly "pure issue of law." Id. at 2137.

DISCUSSION

Mindful that all doubts concerning the propriety of removal are to be resolved in favor of remand, Boyer v. Snap-On Tools Corp., 913 F.2d 108, 111 (3d Cir. 1990), the Court concludes that it must grant the Commonwealth's Motion to Remand because the Complaint does not raise a sufficiently substantial and disputed issue of federal law, and because the exercise of federal

jurisdiction here would upset the “congressionally approved balance of federal and state judicial responsibilities.” See Grable, 545 U.S. at 308.

A. Disputed Federal Issue

As an initial matter, the federal issue must be actually disputed, and essential to the adjudication of the plaintiff’s claim. Id. at 313 (quoting Smith v. Kansas City Title & Trust Co., 255 U.S. 180, 199 (1921)). Thus, in Grable, the action turned on whether the plaintiff had received adequate notice. Because the parties disputed what form of notice was required under the Internal Revenue Code, the interpretation of federal law was essential to the adjudication of the plaintiff’s claim. Grable, 545 U.S. at 315. By contrast, in Pennsylvania v. TAP Pharmaceutical Products, Inc., 415 F. Supp. 2d 516 (E.D. Pa. 2005), the Commonwealth’s Medicaid recovery action based on alleged fraudulent price setting involved a federal standard, but the implicated term “average wholesale price” was not “actually disputed,” and a court would “not need to ascribe any meaning to the words “average wholesale price”” for the plaintiff to prevail. Id. at 524-525. The court in TAP declined to exercise federal jurisdiction because the term “was no more than a federal standard,” and thus did not present a disputed issue of federal law. Id. at 525.

Here, as in Empire and TAP, “liability may proceed on entirely non-federal grounds.” TAP, 415 F. Supp. 2d at 518. The Commonwealth has sued the Defendants for causing the submission of false or fraudulent claims for payment to the Commonwealth’s Medicaid and PACE programs by illegally promoting their respective drugs for non-medically accepted indications and non-medically necessary uses. The prescriptions issued for the off-label uses allegedly constitute “false claims” within the meaning of Pennsylvania law because Medicaid

and PACE reimbursement is not available for non-medically accepted indications and non-medically necessary uses. (Compl. ¶¶ 191, 199.) Even though “medically accepted indication” is defined by federal law, liability under the state law claims presented here nonetheless does not depend on the violation of any federal standard or statute.

The Complaint in this case alleges a series of tortious acts committed by the Defendants with the goal – and result – of increasing submissions of claims for non-medically accepted indications and non-medically necessary uses of each drug. The focus is on the Defendants’ alleged “wide-spread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of their antipsychotic drugs,” as well as the Defendants’ alleged failures to warn and affirmative misrepresentations with respect to known dangerous side effects. (Compl. ¶ 62.) To prevail, the Commonwealth must prove that the Defendants’ fraudulent promotion of their respective drugs caused false or fraudulent claims to be submitted to Medicaid and PACE for reimbursement, and that the Defendants’ failure to provide adequate warnings of known risks caused Commonwealth Medicaid and PACE participants to sustain injuries for which Medicaid and PACE provided treatment. Looked at analytically and closely, no violation of federal law is asserted in the Complaint as a basis for liability.

Thus, while the prescription of the drugs for such “off-label” uses was the alleged goal – and the alleged harm – the submission of claims for non-medically accepted indications or non-medically necessary uses was not in and of itself the tortious conduct. In other words, the central dispute in this case, as in Empire, will be factual. Here, the central question is whether the Defendants’ advertising and promotion methods violate Pennsylvania tort law, not what is or is not a medically accepted indication or medically necessary use. The alleged acts and omissions

by the Defendants allegedly constitute a failure to warn, negligence, breach of warranty, fraud and misrepresentation under Pennsylvania law not merely because the Defendants promoted their drug for off-label uses, but because they allegedly intentionally misrepresented their drug's efficacy and risks for such uses.

The Defendants, however, have focused on Count I of the Complaint, which alleges that the Defendants violated Pennsylvania law by causing the submission of false and fraudulent claims under the Medicaid program. According to the Complaint, the claims submitted as a result of the Defendants' tortious conduct constitute "false" claims under Pennsylvania law *because* "Medicaid reimbursement is not available for non-medically accepted indications or non-medically necessary uses of Zyprexa, Seroquel or Risperdal." (Compl. ¶ 191.)² Therefore, argue the Defendants, resolution of Count I depends upon the meaning of the term "medically accepted indication," which is defined by federal law, and upon whether, absent the Defendants' alleged misrepresentations, federal law would have permitted the Commonwealth to refuse to reimburse prescriptions for non-medically accepted indications.

The Defendants likewise contend that because the marketing of prescription drugs is extensively regulated by the FDA, resolution of the Commonwealth's deceptive marketing claims also requires construction and application of federal law, namely, the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, and its implementing regulations. With respect to the Commonwealth's allegations that the Defendants failed to disclose or warn of the side effects of their respective drugs, the Defendants contend that, in light of the FDA's

² Count II is similar, but based on a different standard, alleging that the Defendants caused the submission of false claims because "PACE reimbursement is not intended for non-medically necessary uses Zyprexa, Seroquel or Risperdal." (Compl. ¶ 199.)

exclusive control over the labeling of medicines, the Commonwealth must necessarily establish that the FDA would have approved the allegedly necessary disclosures and that the Defendants violated the FDCA by marketing their medicines for non-approved uses. Under federal regulations, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4) (2005).

These defense arguments fail to justify removal for two reasons. First, the term “medically accepted indication” is used in the Complaint merely as a common standard that delimits the Medicaid fraud claim, but does not alone present a disputed federal issue. See Merrell Dow, 478 U.S. at 817. Even if the term itself is disputed, it does not define the entire scope of permissible conduct under the Pennsylvania Medicaid statute, the PACE statute, or the common law claims. Simply put, it is not the act of causing the submission of a claim for a non-medically accepted indication that creates liability under the state law causes of action, but rather the act of causing the submission of a *false or fraudulent* claim. A false or fraudulent claim may or may not be submitted for a medically accepted indication.

Similarly, the Commonwealth’s allegation that the Defendants failed to adequately warn Medicaid and PACE participants of the risks associated with their respective drug turns not on a violation of federal labeling standards, but on a violation of Pennsylvania common law. There is no liability asserted in the Complaint for mere failure to comply with federal law. Thus, the Commonwealth’s claims this case, as in Empire, are “fact-bound” and “situation-specific,” and unlike the allegations in Grable, where the meaning of a federal statute was both disputed and an essential element of the plaintiff’s state law cause of action. Grable, 545 U.S. at 314, the allegations presented here do not turn on the interpretation of federal law. Rather, as previously

noted, the central disputes in this case are factual.

Second, with the possible exception of the medically accepted indication standard, the federal “issues” cited by the Defendants are affirmative defenses and, therefore, insufficient to confer subject matter jurisdiction. Merrell Dow, 478 U.S. at 808 (“A defense that raises a federal question is inadequate to confer federal jurisdiction.”) (citing Louisville & Nashville R. Co. v. Mottley, 211 U.S. 149 (1908)); see also United Jersey Banks v. Parell, 783 F.2d 360, 365 (3d Cir. 1986) (“federal jurisdiction cannot be created by anticipating a defense based on federal law”); Guckin v. Nagle, 259 F. Supp. 2d 406, 409 (E.D. Pa. 2003) (“actions are not removable based on the availability of a federal defense to the state law grounded complaint”).

This rule applies “with full force even when the defense involved is one of federal preemption.” Guckin, 259 F. Supp. 2d at 409 (citation omitted); see also Goepel v. Nat’l Postal Mail Handlers Union, 36 F.3d 306, 311 (3d Cir. 1994) (“[I]t is now settled law that a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff’s complaint, and even if both parties concede that the federal defense is the only question truly at issue.”) (quoting Caterpillar, Inc. v. Williams, 482 U.S. 386, 393 (1987)) (emphasis in original).

This rule is excepted where there is “complete preemption” of the state law that serves as the basis for the complaint. Guckin, 259 F. Supp. 2d at 410. The Court of Appeals for the Third Circuit applies complete preemption only where “(1) the federal statute that ostensibly serves as the basis for removal contains civil enforcement provisions within the scope of which the plaintiff’s claim falls, and (2) there is a clear indication of Congressional intent to permit removal.” Goepel, 36 F.3d at 311.

No court has held that the federal Medicaid Act or the FDCA completely preempts a state's Medicaid recovery action for purposes of removal jurisdiction. Indeed, courts in this district have found that removal based on complete preemption by the FDCA is improper because the FDCA does not provide for civil enforcement remedies. See Guckin, 259 F. Supp. 2d at 415 (citing In re Orthopedic Bone Screw Prods. Liability Litig., 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action.")). As the Supreme Court explained in Empire, "[i]f Congress intends a preemption instruction completely to displace ordinarily applicable state law and to confer federal jurisdiction thereby, it may be expected to make that atypical intention clear." Empire, 126 S. Ct. at 2135.

While the state law causes of action presented here may incorporate a federal standard, they do not require the construction or interpretation of a disputed issue of federal law. Thus, the Defendants have failed to satisfy the first prong of Grable.

B. Substantial Federal Issue

"[F]ederal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." Grable, 454 U.S. at 313. In assessing the substantiality of a purported federal interest, courts assess the extent to which exercise of jurisdiction is consistent with Congressional intent. Grable, 545 U.S. at 317 (citing Merrell Dow, 478 U.S. at 810), and look to whether the underlying federal issue is sufficiently "substantial" to demonstrate a clear indication of "a serious federal interest in claiming the advantages thought to be inherent in a federal forum." id. at 313.

As discussed above, the Defendants contend that the Commonwealth's claims raise the

following “substantial” federal issues: (a) whether the Defendants marketed their medicines for uses that were not “medically accepted indications,” as defined by federal law; (b) whether the Commonwealth, consistent with federal Medicare law, could have refused to pay for the prescriptions that the Commonwealth alleges were improperly submitted for reimbursement under its Medicaid program; (c) whether the Defendants violated the FDCA by allegedly marketing their medicines for non-approved uses; and (d) whether the FDA would have permitted the Defendants to modify the FDA-approved labels for the drugs at issue in order to comply with Pennsylvania law. According to the Defendants, these issues implicate the federal Medicaid program and the FDA’s regulation of prescription drugs, and thus require a federal forum to ensure national uniformity. In addition, as previously noted, there are ongoing federal Multi-District Litigation proceedings that include cases analogous to this one.³

³ Federal district courts, however, are split on whether federal jurisdiction is proper with respect to such cases, and the existence of current MDL proceedings does not automatically confer subject matter jurisdiction. In West Virginia ex rel McGraw v. Eli Lilly & Co., 476 F. Supp. 2d 230 (E.D.N.Y. 2007), and In re Zyprexa Products Liability Litigation, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the Eastern District of New York, the court to which the Zyprexa MDL cases are assigned, denied motions to remand in closely analogous cases, holding that “the question of the state’s obligation to reimburse its insureds for [prescriptions drugs], using funds largely provided by the federal government, is essential to the state’s theory of damages and presents a substantial and disputed federal issue under Grable.” West Virginia, 476 F. Supp. 2d at 233; see also In re Zyprexa, 375 F. Supp. 2d at 172-73 (same). West Virginia emphasized that at issue was “not simply a federal standard, but also the added factor of an intricate federal regulatory scheme, including detailed federal funding provisions, requiring some degree of national uniformity in interpretation.” 476 F. Supp. 2d at 234. The district courts for the District of Alaska and for the Western District of Texas, however, granted motions to remand in analogous cases also slated for transfer by the Judicial Panel on Multi-District Litigation. In Texas v. Merck & Co., Inc., 385 F. Supp. 2d 604 (W.D. Tex. 2005), the state of Texas sued a drug manufacturer in state court, alleging that the defendant made misrepresentations about the safety of its drug, which Texas had placed on its Medicaid formulary, and seeking damages and civil penalties pursuant to the Texas Medicaid Fraud Prevention Act. The defendant removed the case to federal court, where the district granted the motion to remand because the particular provisions of the state statute at issue were “not focused on or concerned with any regulations promulgated or enforced by the Food and Drug Administration,” but rather involved “Merck’s

In support of remand, the Commonwealth asserts that because there is no private right of action in either the federal Medicaid legislation or the FDCA, and Congress requires states to seek recovery of Medicaid funds from liable third parties, 42 U.S.C. § 1396(a)(25), Congress did not intend for Section 1331 to encompass state Medicaid recovery actions.

Although federal regulatory schemes may be implicated here, “it takes more than a federal element to open the ‘arising under’ door.” Empire, 126 S. Ct. at 2137. The mere presence of a federal standard embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of the federal statute. Merrell Dow, 478 at 810-14.⁴ Similarly, the fact that a federally created program, Medicaid, serves as the initial source of the funds the Commonwealth seeks to recover does not,

conduct toward and with Texas in requesting and receiving approval from Texas to add VIOXX to Texas’s Medicaid program.” Id. at 608. See also Alaska v. Eli Lilly & Co., No. 06-88, 2006 WL 2168831 (D. Alaska July 28, 2006) (holding that state of Alaska’s state law claims against Eli Lilly for alleged fraud and negligent misrepresentation, strict liability, and violation of state consumer protection statute “do not implicate a substantial federal question” even though federal law was implicated as a “factual predicate”).

⁴ The Court reiterated this point in Grable.

Merrell Dow should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the “sensitive judgments about congressional intent” that § 1331 requires. . . . The Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues. For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action.

Grable, 545 U.S. at 318.

without more, confer federal jurisdiction. Commonwealth of Massachusetts v. Philip Morris, Inc., 942 F. Supp. 690, 694 (D. Mass. 1996); see also Gingerich v. White Pigeon Community Schools, 736 F. Supp. 147 (W.D. Mich. 1990) (holding the receipt and use of federal funds insufficient to confer federal jurisdiction).⁵

As the Supreme Court emphasized in Empire, “[f]ederal courts should await a clear signal from Congress before treating such auxiliary claims as ‘arising under’ the laws of the United States.” Empire, 126 S. Ct. at 2127; see also New York v. Lutheran Center for the Aging, Inc., 957 F. Supp. 393, 403 (E.D.N.Y. 1997) (“[W]here a federal statute such as Medicaid requires a state to enforce liability against a third party but does not provide the ground for that liability, nor require establishment of a ground for liability, federal jurisdiction will not lie.”); Hawaii v. Abbott Laboratories, Inc., No. 06-437, 2006 WL 3457617, at *12 (D. Hawaii Nov. 30, 2006) (noting that “if Congress had thought that [average wholesale price] and other Medicare provisions implicated a substantial federal interest, it could have ensured that only federal courts would hear such cases,” but it did not). Thus, the “critical factor in determining the scope of rights and remedies under a federal statute is the congressional intent behind the particular

⁵ But see Municipality of San Juan v. Corporacion Para El Fomento Economico De La Ciudad Capital, 415 F.3d 145, 148 (1st Cir. 2005) (where the propriety of defendant’s conduct “turns entirely on its adherence to the intricate and detailed set of federal regulatory requirements, and the funds at issue are federal grant monies,” federal jurisdiction proper under Grable); West Virginia, 476 F. Supp. 2d 230 (holding that “the question of the state’s obligation to reimburse its insureds for [prescription drug] using funds largely provided by the federal government, is essential to the state’s theory of damages and presents a substantial and disputed federal issue under Grable”); In re Zyprexa, 375 F. Supp. 2d 170 (same); In re Pharmaceutical Indus. Average Wholesale Price Litig., 457 F. Supp. 2d 77, 81 (D. Mass. 2006) (holding that interpretation of “average wholesale price” provision of federal Medicare statute raises substantial federal question and that assertion of federal jurisdiction was “unlikely to upset any balance because of the substantial number of similar cases that are already pending in federal courts”).

provision at issue.” Empire, 126 S. Ct. at 2134 (citation omitted).

There is no meaningful indication that Congress intended to confer federal jurisdiction over state law causes of actions implicating the federal statutes involved here, namely, the FDCA and Title XIX of the Social Security Act, 42 U.S.C. §1396, *et seq.*, which is the federal legislation establishing the Medicaid program. Considering the absence of a federal cause of action in FDCA, the Supreme Court held that “the Congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a Congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently ‘substantial’ to confer federal-question jurisdiction.” Merrell Dow, 478 U.S. at 814.

Likewise, under Title XIX, the “Federal Government shares the costs of Medicaid with States that elect to participate in the program. In return, participating States are to comply with requirements imposed by the Act and by the Secretary of Health and Human Services.” Atkins v. Rivera, 477 U.S. 154, 156-57 (1986). A state electing to participate in the Medicaid program must submit a state plan that, among other things, requires that the state “take all reasonable measures to ascertain the legal liability of third parties . . . to pay for care and services available under the plan...” 42 U.S.C. §1396a(a)(25). If “legal liability is found to exist,” the state must seek reimbursement “to the extent of such legal liability” Id. Critically, Title XIX does not create a cause of action for seeking such reimbursement. Rather, states electing to pursue liable third parties must do so using state law based theories.

Due to the absence of any indication of congressional intent to confer federal jurisdiction over claims involving the FDCA or Title XIX, the Defendants also fail to demonstrate the

requisite substantiality required by Grable.

C. Federalism and Comity

“[E]ven when the state action discloses a contested and substantial federal question, the exercise of federal jurisdiction is subject to a possible veto.” Grable, 545 U.S. at 313, because courts must consider the nature of the federal and state interests and the resulting effect that exercise of jurisdiction would have on the traditional balance of responsibilities between state and federal courts. Id. at 313-14. The proper “arising under” jurisdiction inquiry is, “does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” Id. at 314. Thus, “the federal issue will ultimately qualify for a federal forum only if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331.” Id.

“Because arising-under jurisdiction to hear a state-law claim always raises the possibility of upsetting the state-federal line drawn (or at least assumed) by Congress, the presence of a disputed federal issue and the ostensible importance of a federal forum are never necessarily dispositive; there must always be an assessment of any disruptive portent in exercising federal jurisdiction.” Grable, 545 U.S. at 314. Such federalism concerns carry additional weight when applied to claims brought by the states. The Supreme Court has colorfully noted that “considerations of comity make us reluctant to snatch cases which a State has brought from the courts of that State, unless some clear rule demands it.” Franchise Tax Bd., 463 U.S. at 22 n.22.

Adjudication of the state law claims presented here will not conflict with or otherwise

disturb the federal interest in and need for uniformity with respect to the regulatory schemes governing prescription medications and Medicaid. The exercise of federal jurisdiction, however, would upset the balance between state and federal courts because it would, in direct contravention of Merrell Dow and Grable, open the federal courthouse to any number of state law causes of actions that invoke a federal standard or stand against the backdrop of a federal regulatory scheme. Where such claims are fact-specific and wholly based on state law, federal jurisdiction will neither further national uniformity, nor ensure the correct precedential interpretation of federal law. Rather, the federal court would be engaged primarily in the interpretation and application of state law, a task better left to the state courts, particularly where there is no indication that Congress intended to confer federal court jurisdiction. Moreover, any interest the federal government may have in a federal forum must be balanced with the Commonwealth of Pennsylvania's interest in developing its law.⁶

In sum, this case cannot be squeezed into the "special and small category" of cases that Grable exemplifies. See Empire, 126 S. Ct. at 2136.

CONCLUSION

Because the Defendants have failed to satisfy their burden of demonstrating that the state law causes of action presented here raise a disputed and substantial question of federal law, and because the Court's exercise of jurisdiction would contravene principles of federalism and comity, the Court must grant the Motion to Remand. An Order consistent with this Memorandum follows.

⁶ See Richard Freer, Of Rules and Standards: Reconciling Statutory Limitations On "Arising Under" Jurisdiction 53 (Public Law & Legal Theory Research Paper Series, Research Paper No. 06-26), available at <http://papers.ssrn.com/abstract=946036>.

BY THE COURT:

S/Gene E.K. Pratter

GENE E.K. PRATTER
United States District Court

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 United States District Court